

**IN THE UNITED STATES DISTRICT COURT
FOR DISTRICT OF SOUTH CAROLINA
Charleston Division**

DEREK CLEMENTS, CADE KLOSTER,)
 ZACH POKRANT, JAMES VASILIU,)
 JUDSON BABCOCK, ANDY BAUMANN,)
 LANCE CAREY, JENNIFER HALL,)
 CONNER WILBURN, JOSIAH BEGGS,)
 AMELIA CASS, JAKE FORD,)
 EZRA PAUL, CALEB PYM,)
 RACHEL SHAFFER, AARON STAIGER,)
 NATHAN SUESS, ROMAN PENNEY,)
 ANDREW WOJTKOW, NATHAN AIME,)
 TABITHA AIME, SOPHIA GALDAMEZ,)
 DAYNA JOHNSON, JIN JOHNSON)

Plaintiffs,

v.

Civil Action No.: 2:22-cv-02069-RMG

LLOYD J. AUSTIN, III)
 Secretary of Defense)
 Department of Defense)

Defendant.

[PROPOSED] FIRST AMENDED COMPLAINT

Military actions are not exempt from judicial review, and federal district courts have the authority to enjoin the military from enforcing a decision that is arbitrary, capricious, contrary to law, and unconstitutional. Similarly, the military is required to follow its own rules, should it choose to promulgate them.

Defendant Secretary of Defense Lloyd Austin, III's decision to require all service members to receive an unapproved and unlicensed SARS-CoV-2 ("COVID-19") vaccine disregards his own agency's requirements to determine whether an individual vaccine recipient

has natural immunity. Defendant’s order establishing a mandatory vaccination program is arbitrary, capricious, contrary to service regulation and federal law, and unconstitutional. Plaintiffs—comprised of service academy cadets, and active duty and Reserve officers and enlisted personnel of the Armed Forces and Coast Guard—now turn to this Court with a plea for relief.

PARTIES

1. Plaintiff Derek Clements is a Technical Sergeant (“TSgt”) in the United States Air Force with over 17 years of service, currently stationed at Joint Base Charleston, South Carolina. He was ordered on April 18, 2022, to begin a vaccine “regimen” within 5 calendar days. TSgt Clements has already received a Letter of Admonishment and Letter of Reprimand for not taking the vaccine for violation of a “lawful” order under Article 92, Uniform Code of Military Justice (“UCMJ”), and faces further adverse disciplinary action, including involuntary separation with a less than honorable characterization of service.¹
2. Plaintiff Cade Kloster is a Senior Airman (“SrA”) in the United States Air Force stationed at Joint Base Charleston, South Carolina. He has natural immunity from a prior COVID-19 infection, as confirmed through a positive antibody test. He has been ordered to receive a COVID-19 vaccine by June 27, 2022, or face separation with a less than honorable characterization of service.
3. Plaintiff Zach Pokrant is a Captain (“Capt”) in the United States Air Force stationed at Joint Base Charleston, South Carolina. He has natural immunity from a prior COVID-19 infection,

¹ The Air Force had a preliminary injunction granted against it in *Doster, et al. v. Kendall, et al.*, Case No. 1:22-cv-00084, (S.D. Ohio), and all Air Force personnel who submitted religious accommodation requests were certified as a class. This includes all Air Force plaintiffs in this case.

as confirmed through an antibody test. Capt Pokrant faces likely adverse disciplinary action for vaccine refusal, including potential separation with a less than honorable characterization of service.

4. Plaintiff James Vasiliu is a SrA in the United States Air Force stationed at Joint Base Charleston, South Carolina. He has natural immunity from a prior COVID-19 infection in September 2021. He has been ordered to receive a COVID-19 vaccine or else face further disciplinary action and involuntary separation with a less than honorable characterization of service for violating Article 92, UCMJ.
5. Plaintiff Judson Babcock is a Lieutenant Colonel (“Lt Col”) in the United States Air Force, stationed at the United States Air Force Academy (“USAFA”), Colorado Springs, Colorado. He has natural immunity from a COVID-19 infection in April 2021. Lt Col Babcock’s religious and medical accommodation requests have both been denied, and he now faces likely adverse disciplinary action and separation.
6. Plaintiff Andy Baumann is a Major (“Maj”) in the United States Air Force Reserve, with over 18 years of service. He presently serves with the Air Force Reserve Command Force Generation Center, Robbins Air Force Base, Georgia. He has natural immunity, as indicated by a monitored COVID-19 antigen test conducted in January 2022. Maj Baumann has already received a Letter of Reprimand and has been told he faces involuntary removal to the Individual Ready Reserve—a process with no notice/response or appeal process. Maj Baumann has been informed that the paperwork for affecting said movement has already been prepared.
7. Plaintiff Lance Carey is a TSgt in the Air Force stationed at Fort Gordon, Georgia. He has natural immunity from a prior COVID-19 infection. On June 3, 2022, TSgt Carey was

ordered to initiate a vaccination “regimen” within 5 calendar days, or face initiation of involuntary separation with a less than honorable characterization of service.²

8. Plaintiff Jennifer Hall is a recently promoted Colonel (“Col”) in the United States Air Force, serving as a Professor of Strategy and Security Studies at Air University, Maxwell Air Force Base, Alabama. Her religious accommodation request and appeals were denied. In response, Col Hall submitted a request to retire, in accordance with Air Force policy following a denial of a Religious Accommodation Request. Defendant Secretary of the Air Force denied her request on May 25, 2022, stating that she failed to demonstrate her early separation was “in the best interest of the Air Force . . . given the overall health of [her] career field.” In conclusion, the denial “recognizes the applicant may be subject to administrative discharge actions for refusal to obey a lawful order to receive the COVID-19 vaccine.” She has since been ordered to be fully vaccinated by July 22, 2022, or face adverse disciplinary and punitive action under the UCMJ. If involuntarily separated, she faces substantial recoupment of service bonuses, and the possibility of reduction to a much lower rank, thereby resulting in a potential near 40% reduction in anticipated retirement pay.
9. Plaintiff Conner Wilburn is a Capt in the United States Air Force, stationed at Fairchild Air Force Base, Washington. His travel has been substantially restricted, thereby denying his access to training and hindering his ability to progress in his career. Capt Wilburn faces further adverse disciplinary action for vaccine refusal, including potential separation with a less than honorable characterization of service. As a graduate of the USAFA, Capt Wilburn also has a year left on his service academy commitment and 8 years left on his Active Duty

² TSgt Carey was also recently selected for promotion to Master Sergeant, to be affected in October 2022, and yet will likely be prevented from advancing to this rank.

Service Commitment, meaning that he could be subjected to forced recoupment if he is discharged with less than honorable characterization of service.

10. Plaintiff Josiah Beggs recently completed his first year as a cadet at USAFA. He has natural immunity from a prior COVID-19 infection. Cadet Beggs received a Letter of Reprimand on May 9, 2022, and has been told that unless he begins a COVID-19 vaccine regimen by August 1, 2022, he will be disenrolled effective that date.
11. Plaintiff Amelia Cass recently completed her first year as a cadet at USAFA. She has natural immunity from a prior COVID-19 infection. Cadet Cass has a temporary medical waiver but is subject to disenrollment once the medical waiver is no longer valid.
12. Plaintiff Jake Ford recently completed his first year as a cadet at USAFA. He has prior immunity from a COVID-19 infection in January 2022. Cadet Ford has already received a Letter of Reprimand for refusing to comply with the vaccine order, and faces further adverse disciplinary action for vaccine refusal, including disenrollment.
13. Plaintiff Ezra Paul recently completed his second year as a cadet at USAFA. He has natural immunity from a prior COVID-19 infection, as confirmed via an antibody test in March 2022. Cadet Paul faces adverse disciplinary action for vaccine refusal, including disenrollment.
14. Plaintiff Caleb Pym recently completed his first year as a cadet at USAFA. He has natural immunity from a prior COVID-19 infection, as confirmed via a positive test on August 15, 2021. On April 13, 2022, Cadet Pym was ordered to receive the COVID-19 vaccine or face certain disciplinary action and processing for involuntary disenrollment from the Academy.
15. Plaintiff Rachel Shaffer recently completed her third year as a cadet at USAFA. She has natural immunity from a prior COVID-19 infection in March 2021, as confirmed via an

antibody test in April 2022. On April 2, 2022, Cadet Shaffer was ordered to receive the COVID-19 vaccine or face certain disciplinary action and processing for involuntary dismissal from the Academy. Because she has “committed” to the Air Force and served in excess of two years at the Academy, she will also be subjected to recoupment of her educational costs.

16. Plaintiff Aaron Staiger is a first-year cadet at USAFA. He has natural immunity from a prior COVID-19 infection in August 2021, as confirmed via an antibody test in April 2022. He has been allowed to enter the Academy due to a temporary medical waiver; if the waiver is revoked, he faces disenrollment.
17. Plaintiff Nathan Suess recently completed his fourth year as a cadet at USAFA. He has natural immunity to COVID-19 as confirmed via an antibody test on June 20, 2022. Although Cadet Suess was permitted to graduate and obtain his degree, his commission is being withheld, he was placed into no-pay post-graduation status, and he now faces dismissal from the Academy and forced recoupment of his educational costs.³
18. Plaintiff Roman Penney recently completed his first year as a cadet at the United States Military Academy (“USMA”), West Point, New York. Cadet Penney faces adverse disciplinary action for vaccine refusal, including potential disenrollment.
19. Plaintiff Andrew Wojtkow recently completed his first year as a cadet at USMA. He has natural immunity to COVID-19 from a prior infection. Cadet Wojtkow faces adverse disciplinary action for vaccine refusal, including potential disenrollment.

³ Illustrative of the many sacrifices made by cadets and service members in service to their country, Cadet Suess is not permitted to marry his fiancé while still a cadet, as rules prohibit cadets from marrying. Accordingly, the withholding of his commission has forced Cadet Suess and his fiancé to postpone his scheduled wedding.

20. Plaintiff Nathan Aime is a cadet at the United States Coast Guard Academy (“USCGA”), New London, Connecticut. He has natural immunity from a previous COVID-19 infection in February 2021, as subsequently confirmed by a COVID antibody test conducted in March 2022. He has been subjected to two separate negative counselings (“Page 7”). His second Page 7 was issued on June 13, 2022, and directed him to receive the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. He was notified by Rear Admiral (“RAMD”) Kelly, Superintendent of USCGA, on June 23 that he is being immediately disenrolled from the Academy. He has until June 30, 2022, to submit an appeal, which is likely to be denied. If denied, he will be immediately disenrolled.
21. Plaintiff Tabitha Aime is a cadet at USCGA. She has natural immunity from a previous COVID-19 infection in January 2021, and as subsequently confirmed by a COVID antibody test conducted in March 2022. She has been subjected to two Page 7 counselings; her second Page 7 was issued on June 13, 2022, and directed her to receive the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. She was notified on June 23 that she is being immediately disenrolled from the Academy. She has until June 30, 2022, to submit an appeal, which is likely to be denied. If denied, she will be immediately disenrolled.
22. Plaintiff Sophia Galdamez recently completed her third year as a cadet at USCGA. She has natural immunity from a prior COVID-19 infection. She has been subjected to two Page 7 counselings; her second Page 7 was issued on June 13, 2022, and directed her to receive the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. She was notified on June 23 that she is being immediately disenrolled from the Academy. She has until June 30, 2022, to submit an appeal, which is likely to be denied. If denied, she will be immediately disenrolled.

23. Plaintiff Dayna Johnson recently completed her first year as a cadet at USCGA. She has been subjected to two Page 7 counselings; her second Page 7 was issued on June 13, 2022, and directed her to receive the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. She was notified on June 23 that she is being immediately disenrolled from the Academy. She has until June 30, 2022, to submit an appeal, which is likely to be denied. If denied, she will be immediately disenrolled.
24. Plaintiff Jin Johnson recently completed his third year as a cadet at USCGA. He has been subjected to two Page 7 counselings; his second Page 7 was issued on June 13, 2022, and directed him to receive the first of two COVID-19 vaccines within five (5) business days—or June 21, 2022. He was notified on June 23 that he is being immediately disenrolled from the Academy. He has until June 30, 2022, to submit an appeal, which is likely to be denied. If denied, he will be immediately disenrolled.
25. Each Plaintiff, to date, has not been tested by the respective service for prior immunity.
26. Upon best information and belief, each Plaintiff, to date, has not been offered a vaccine licensed by the Food and Drug Administration (“FDA”).
27. Defendant Lloyd J. Austin, III, Secretary of Defense, Department of Defense, mandated that all service members and cadets be “fully vaccinated” with a licensed vaccine—despite the licensed vaccine being unavailable in the United States—against COVID-19, and provide proof of said vaccination, or face disciplinary action, up to and including involuntary separation from the military. The Department of Defense is present in, and conducts business in, this District.

JURISDICTION AND VENUE

28. This action is brought under the Administrative Procedure Act (APA), 5 U.S.C. § 701, *et*

seq., challenging the unlawful and unconstitutional nature of the mandates.

29. The APA provides the Court with the authority to review final agency action to determine if it is arbitrary, capricious, unsupported by evidence, contrary to law, or unconstitutional.
30. The declaratory relief requested herein is proper under 5 U.S.C. §§ 706(1)-(2) and 21 U.S.C. §§ 2201 and 2202.
31. Venue is proper in this Court under 28 U.S.C. § 1391(e)(1) and 28 U.S.C. § 141402(a)(1), because this is the judicial district in which Defendant and several Plaintiffs are located. All Plaintiffs have a common question of law with respect to the lawfulness of the vaccine mandate's requirement to use EUA vaccines, and the arbitrary and capricious nature of the mandate.

STATEMENT OF FACTS

Development of Vaccines

32. Upon best information and belief, the novel COVID-19 infection first arrived in the United States in or around January 2020. Just a few short months later, then President Trump directed the immediate development of a vaccine under Operation "Warp Speed." This condensed an otherwise decades-long vaccine development process into less than one year.
33. From this endeavor were born three vaccines that were, and are, widely available in the United States: the Pfizer-BioNTech COVID-19 vaccine, the Moderna COVID-19 vaccine, and Johnson & Johnson's Janssen COVID-19 vaccine.⁴ None of these vaccines are licensed

⁴ The Johnson & Johnson vaccine is a viral vector vaccine, not mRNA. Nevertheless, the CDC encourages individuals to receive an mRNA vaccine over the Johnson & Johnson vaccine. *Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety*, Ctrs. for Disease Control & Prevention (June 10, 2022), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html> (last visited June 28, 2022).

by the FDA; rather, they were authorized for emergency use under Section 564 of the Food, Drug, and Cometic Act, 21 U.S.C. § 360bbb-3.

34. The Pfizer-BioNTech vaccine received EUA status on December 11, 2020.⁵ Approval was based on a study of BNT162b2, which was distributed as a frozen suspension (-80°C to -60°C) that must be thawed and diluted with 1.8 mL of sterile 0.9% sodium chloride.⁶

35. On August 23, 2021, the FDA approved the Pfizer-BioNTech’s Biologics License Application (“BLA”) for this specific product and authorized the companies to jointly market the product as “COMIRNATY.”⁷

36. COMIRNATY is “legally distinct with certain differences” from the Pfizer-BioNTech COVID-19 vaccine that was authorized for emergency use in December 2020.

37. Simultaneous with the licensing of COMIRNATY, the FDA reissued EUA approval for the Pfizer-BioNTech vaccine, stating that “[t]here is no adequate, approved, and available alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine.”⁸ The EUA approval letter also noted there were insufficient stocks of the COMIRNATY “approved vaccine” available for distribution. This language is consistent with 21 U.S.C. §360bbb-

⁵ U.S. Food & Drug Admin., EUA for an Unapproved Product Review Memorandum, <https://www.fda.gov/media/144416/download> (last visited June 16, 2022).

⁶ *Id.*

⁷ U.S. Food & Drug Admin., BioNTech Manufacturing GmbH Biologics License Application Approval (Aug. 23, 2021), <https://www.fda.gov/media/151710/download> (last visited Jan. 3, 2022).

⁸ U.S. Food & Drug. Admin, Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (Aug. 23, 2021), <http://web.archive.org/web/20210823142928/https://www.fda.gov/media/150386/download> (last visited June 21, 2022)

3(c)(3), which states that an EUA cannot be issued unless “there is no adequate, approved, and available alternative to the product.”

38. On November 18, 2021, Pfizer-BioNTech submitted a supplemental BLA requesting to change the formula of COMIRNATY to a Tris/Sucrose base that did not require dilution—unlike the originally tested and approved COMIRNATY. The FDA issued an approval letter of the supplemental BLA less than a month later on December 16, 2021.⁹ Whereas the “first” COMIRNATY was to be distributed with a purple-colored cap and bottle label, this “second” COMIRNATY is to be distributed with a gray-colored cap and bottle label. The gray-colored vials were not intended to be marketed until May 18, 2022.¹⁰
39. To reiterate, the Pfizer-BioNTech vaccine, to this date, remains under EUA (last reissued on June 17, 2022), with a statutory determination that there is no “adequate, approved, and available alternative to the product.”¹¹ The Moderna and Johnson & Johnson’s Janssen COVID-19 vaccine, similarly, remain under EUA.¹²

⁹ U.S. Food & Drug Admin., BioNTech BLA Supplemental Approval (Dec. 16, 2021), <https://www.fda.gov/media/154939/download> (last visited June 21, 2022).

¹⁰ U.S. Food & Drug Admin., COMIRNTAY Gray Label Insert, <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=48c86164-de07-4041-b9dc-f2b5744714e5&type=display> (last visited Jun. 27, 2022).

¹¹ U.S. Food & Drug Admin., Letter of Authorization – Pfizer-BioNTech (reissuing authorization) (June 17, 2022), <https://www.fda.gov/media/150386/download> (last visited June 21, 2022).

¹² U.S. Food & Drug Admin., Letter of Authorization – Janssen COVID-19 Vaccine (reissuing authorization) (May 5, 2022), <https://www.fda.gov/media/146303/download> (last visited Jan. 3, 2022); Letter of Authorization – Moderna (reissuing authorization), U.S. Food & Drug Admin. (Mar. 29, 2022), <https://www.fda.gov/media/144636/download> (last visited June 21, 2022).

Military Mandates

40. On August 9, 2021, Defendant Secretary of Defense Austin issued a memorandum notifying the entire Department of Defense (“DoD”) that the President had asked him “to consider how and when [DoD] might add the coronavirus disease 2019 (COVID-19) vaccines to the list of those required for all Service members.”¹³ Defendant Secretary of Defense Austin stated that he would issue a mandate by either first seeking the President’s approval by mid-September to use an EUA vaccine, or upon approval of a vaccine by the FDA, whichever occurred first.¹⁴
41. Defendant Secretary of Defense Austin wasted no time in issuing the mandate once the FDA “licensed” COMIRNATY on August 23, 2021. The very next day, August 24, 2021, he mandated all service members must receive “full vaccination” against COVID-19 via inoculation with a “fully licensed” vaccine.¹⁵
42. Service members with prior COVID-19 infection and immunity would not be considered fully vaccinated.¹⁶

¹³ Sec’y of Def., Message to the Force (Aug. 9, 2021), <https://media.defense.gov/2021/Aug/09/2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF> (last visited June 21, 2022).

¹⁴ *Id.*

¹⁵ Sec’y of Def., Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members (Aug. 24, 2021), <https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONAVIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF> (last visited June 21, 2022).

¹⁶ *Id.*

43. ADM Fagan¹⁷ issued a Coast Guard order two days later, on August 26, 2021, wholly adopting Defendant Secretary of Defense Austin’s August 24 memorandum.¹⁸ Even more worrisome is that ADM Fagan specifically required inoculation with the unlicensed Pfizer-BioNTech vaccine, not the “licensed,” and unavailable, COMMIRNATY.¹⁹ This requirement to be inoculated with an unlicensed vaccine showed just how little attention was paid by the services in rushing through this mandate.
44. Each of the Armed Services, including the Coast Guard, has issued implementation guidance that requires either compliance or certain disciplinary action, including likely involuntary separation from the service with a possible stigmatizing less-than-honorable characterization of service.

Unlawful Nature of the Mandate

45. The military COVID-19 vaccine mandate (a collection of the mandates and orders issued by Secretary of Defense Austin, and filtered down through various high-level subordinates in the respective Services) was purposefully issued in violation, and without consideration, of federal statutes and service regulations.

Military Regulation on Natural Immunity

46. Joint Services Regulation, “Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases,” October 7, 2013, issued as Army Regulation (AR) 40-562, Air Force Instruction (AFI) 48-110_IP, and Coast Guard Commandant Instruction (“COMDTINST”)

¹⁷ The order itself was issued by her predecessor, but as ADM Fagan is the current Commandant, all historical facts will reference her for continuity purposes.

¹⁸ ALCOAST 305/21 (Aug. 26, 2021).

¹⁹ *Id.*

M6230.4G,²⁰ “provides directive requirements for the Military Vaccination Program; establishes general principles, procedures, policies, and responsibilities for the immunization program; and implements military and international health regulations and requirements.”²¹

47. This regulation is unequivocal in its requirement that before being administered a mandatory vaccine, the service member will be tested for prior immunity.²²

48. Prior immunization, per this regulation, shall be treated as a medical exemption from a required vaccine.²³

49. Underscoring this requirement to test service members for prior immunity is the science regarding the efficacy of natural immunity to COVID-19. At the time the memorandum mandate was issued, DoD had information that demonstrated the efficacy of previous infection against reinfection, and also possessed information detailing the ineffectiveness of the vaccines in preventing or reducing COVID-19 transmissibility. Notably, a June 2021 study conducted by the revered Cleveland clinic found that individuals previously infected

²⁰ For ease of reference, this regulation will be cited to AR 40-562, even though it applies to all Services.

²¹ AR 40-562 at ¶1-1.

²² *Id.* at ¶¶ 1-4.c.(4) (“Medical commanders, commanding officers, and command surgeons: Ensure patients are evaluated for preexisting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications.”); 2-6.a.(1)(b) (a medical exemption is warranted with “[e]vidence of immunity based on serologic tests, documented infection, or similar circumstances.”); 3-1.a.(2) “(Immunize if the primary series is incomplete, if a booster immunization is needed, or if the Service personnel has no serologic or documented evidence of immunity.”); 3-1.a.(3) (“Before immunizing, conduct serologic testing where available.”); and 3.1.e. (“Upon accession, screen commissioned and warrant officers for immunization *or immunity status* and vaccinate as required.”).

²³ *Id.* at Appendix C, table C-1 (medical exemption code MI, which stands for (medical, immune)).

with COVID-19 did not suffer reinfection, and that ultimately, “Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination.”

FDA License v. EUA Status

50. 10 U.S.C § 1107a unambiguously requires informed consent by service members—with the option to refuse—prior to receipt of an EUA product. This requirement for informed consent can only be waived, in writing, by the President.²⁴
51. The Secretary of Defense is required to abide by this proscription: allow informed consent, with the opportunity to refuse without adverse consequences, or seek the President’s written approval for use of an EUA product.²⁵
52. Defendant Secretary of Defense Austin knew, as of August 23, 2021, that COMIRNATY was not available in the United States nor was it to be manufactured and distributed in the United States; and yet, Secretary Austin summarily disregarded statutes and regulation, and ordered that service members be inoculated with an EUA vaccine.
53. To circumvent the requirement to obtain the President’s written approval to use an EUA, Defendant Secretary of Defense Austin has affirmatively stated the Pfizer-BioNTech vaccine and COMIRNATY are interchangeable.
54. “Interchangeable” and “interchangeability” are specifically defined terms in Section 351 of the Public Health Service Act (“PHSA”) governing the regulation of biologics, 42 U.S.C. §

²⁴ 10 U.S.C. § 1107a(a)(1).

²⁵ DoD Instruction (DoDI) 6200.02 at ¶¶5.2.2, 5.2.3.

262,²⁶ in relation to a “reference product,”²⁷ which is a biological product licensed under Section 351(a) of the PHSA. 42 U.S.C. § 262(a).²⁸

55. For the purposes of determining “interchangeability,” the “reference product” must be an FDA-licensed product; in this case, the FDA licensed COMIRNATY vaccine. But the “interchangeable” product, the EUA Pfizer-BioNTech Vaccine, must be the subject of a later filed “abbreviated” application under 42 U.S.C. § 262(k), and there is no indication that any such application was ever filed by BioNTech, much less reviewed or approved by the FDA.
56. Thus, the Pfizer-BioNTech vaccine and COMIRNATY are not legally interchangeable.

FIRST CAUSE OF ACTION
(Administrative Procedure Act)

DoD’s Vaccine Mandate Order is Arbitrary and Capricious, and Contrary to Law.
Defendant Specifically Issued These Orders Knowing It Was in Violation of 10 U.S.C. § 1107a and DoDI 6200.02, and the Mandate Orders Remain in Violation of this Statute and Regulation.

²⁶ “Interchangeable” and “interchangeability” are defined as a “biological product” that “may be substituted for the reference product” by health care providers. 42 U.S.C. § 351(i)(3). To meet the standards in 42 U.S.C. § 262(k)(4) (“Safety standards for determining interchangeability”), the “interchangeable” or substitute biological product (i) must be biosimilar to the reference product, and (ii) “can be expected to produce the same clinical result as the reference product in any given patient.” 42 U.S.C. § 262(k)(4).

²⁷ “Reference product” is defined as “the single biological product licensed” under 42 U.S.C. § 262(a) “against which a biological product is submitted” under 42 U.S.C. § 262(k). 42 U.S.C. § 351(i)(4).

²⁸ These definitions and related provisions were enacted as part of the Biologics Price Competition Act of 2009, which “amends the PHSA and other statutes to create an abbreviated licensure pathway,” under Section 351(k) of the PHSA, 42 U.S.C. § 262(k), “for biological products shown to be interchangeable with an FDA-licensed biological reference product,” licensed under Section 351(a) of the PHS Act, 42 U.S.C. § 262(a). *See generally* U.S. Food & Drug Admin, *et al.*, Considerations in Demonstrating Interchangeability with a Reference Product: Guidance for Industry (May 2019), <https://www.fda.gov/media/124907/download> (last visited June 23, 2022).

57. Plaintiffs incorporate paragraphs 32-56 as though fully set forth herein.
58. The APA permits federal District Courts to review final agency action and enjoin the above executive entities from enforcing orders that are arbitrary, capricious, and contrary to law and regulation.
59. “Final agency action” is one from which legal consequences will flow.
60. The vaccine mandate constitutes final agency action because all Plaintiffs are required to either receive a COVID-19 vaccine or face adverse disciplinary action and involuntary separation from the service absent an approved accommodation.
61. As of August 10, 2021, Defendant Secretary of Defense Austin recognized that he needed a written Presidential waiver prior to requiring service members be involuntarily inoculated with an EUA approved vaccine.
62. When the FDA licensed COMIRNATY on August 23, 2021, it simultaneously reissued the EUA status for the Pfizer-BioNTech vaccine, recognizing that there was no COMIRNATY product available in the United States.
63. Despite this explicit recognition by the FDA that an FDA licensed product did not exist in the United States, Defendant Secretary of Defense Austin ordered all service members be inoculated with the EUA Pfizer-BioNTech vaccine.
64. At no point did Defendant Secretary of Defense Austin seek written waiver by the President.
65. Similarly, ADM Fagan issued an order, wholly adopting Defendant Secretary of Defense Austin’s August 24, 2021, order, and required that all service members in the Coast Guard receive the unlicensed EUA Pfizer-BioNTech vaccine.
66. The mandate was issued with knowledge that no FDA licensed product was available and that service members could not be forced to receive a non-licensed vaccine absent written

Presidential waiver.

67. Defendant Secretary of Defense Austin’s purposeful violation of federal law when issuing these orders renders the order arbitrary and capricious.
68. Furthermore, given the FDA’s reissuance of the Pfizer-BioNTech EUA on June 17, 2022, the FDA’s reissuance of the Moderna EUA on March 29, 2022, and the reissuance of the Johnson & Johnson EUA on May 5, 2022, the mandate is still in violation of 10 U.S.C. § 1107a and DoDI 6200.02 because the FDA has explicitly recognized that no “adequate, approved, and available alternative to the product” exists in the United States.
69. Because the mandate is arbitrary, capricious, and unlawful, this Court should enjoin the Defendant and its Services from enforcing it.

SECOND CAUSE OF ACTION
(Administrative Procedure Act)

Defendant’s Order Violates Regulations that Prohibit Forced Inoculations Without Consideration of an Individual’s Personal Factors Like Previous Infection.

70. Plaintiffs incorporate paragraphs 32-56 as though fully set forth herein.
71. The APA permits federal District Courts to review final agency action and enjoin enforcement if it is in violation of service regulations.
72. Final agency action is one from which legal consequences will flow.
73. The vaccine mandate constitutes final agency action as all Plaintiffs are required to either receive a COVID-19 vaccine or face involuntary separation from the service.
74. Under AR 40-562, as applicable to all services, prior and natural immunity is a basis for a medical exemption from an involuntary inoculation.
75. Accordingly, commanders are required to determine prior or natural immunity before forcing a service member to involuntarily receive a mandated vaccine.

76. Defendant Secretary of Defense Austin's August 24, 2021, mandate explicitly states prior and natural immunity will not be considered.
77. Each Service, in implementing Defendant's mandate, has similarly refused to consider prior and natural immunity as a proper medical exemption, and no Plaintiff has been tested for prior natural immunity.
78. Defendant's purposeful violation of service regulations renders the mandate unlawful, and this Court should enjoin it from further enforcement.

THIRD CAUSE OF ACTION
(Administrative Procedure Act)

Defendant's Order Contravenes DoD Regulation, and Results in a Violation of Plaintiff's Constitutional Right to Procedural Due Process Under the Fifth Amendment.

79. Plaintiffs incorporate paragraphs 32-56 as though fully set forth herein.
80. The APA permits federal District Courts to review final agency action and enjoin enforcement if it is in violation of the constitution.
81. Final agency action is one from which legal consequences will flow.
82. The vaccine mandate constitutes final agency action as all Plaintiffs are required to either receive a COVID-19 vaccine or face involuntary separation from the service.
83. The Fifth Amendment to the United States Constitution affords service members procedural due process.
84. When services fail to follow their own regulations, should they choose to promulgate them, they violate the afflicted service member's constitutional right to procedural due process.
85. AR 40-562, as applicable to all services, requires medical exemptions from involuntary vaccines for those with prior and natural immunity.
86. Defendant purposefully disregarded this regulatory requirement, and in turn violates

Plaintiffs' constitutional right to procedural due process.

87. Furthermore, DoDI 6200.02 requires informed consent, with an option to refuse, when a service member is required to be inoculated with an EUA vaccine.

88. Defendant issued the mandate, and continues to enforce the mandate, in knowing violation of this requirement. In turn, Defendant violates Plaintiffs' constitutional right to procedural due process.

89. Accordingly, this Court should find the orders are violative of Plaintiffs' constitutional right to procedural due process and enjoin Defendant from enforcing them.

RELIEF

Wherefore, Plaintiffs respectfully pray that this Honorable Court:

- (1) Declare the DoD Mandate void because it is arbitrary, capricious, unlawful, and unconstitutional;
- (2) Enjoin any implementation of the DoD Mandate;
- (3) Award reasonable attorneys' fees and allowable costs under the Equal Access to Justice Act; and
- (4) Award any further relief this Honorable Court deems necessary or appropriate in order to accord full and complete relief.

Dated: August 1, 2022

Respectfully Submitted,

/s/ Michael T. Rose

Michael T. Rose (S.C. Bar No. 0004910)

Mike Rose Law Firm, PC

409 Central Ave.

Summerville, SC 29483

Telephone: (843) 875 6856

mike@mikeroselawfirm.com

Local Counsel

/s/ Carol A. Thompson

Carol A. Thompson

Federal Practice Group

1750 K Street N.W., Suite 900
Washington, D.C. 20006
Telephone: (202)862-4360
Facsimile: (888)899-6053
cthompson@fedpractice.com
Admitted Via Pro Hac Vice

/s/ John J. Michels, Jr.
John J. Michels, Jr.
Federal Practice Group
1750 K Street N.W., Suite 900
Washington, D.C. 20006
Telephone: (202)862-4360
Facsimile: (888)899-6053
lmichels@fedpractice.com
Admitted via Pro Hac Vice

Counsel for Plaintiffs